IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	**CIVIL ACTION**
***ex rel.* AARON SHILOH, M.D., FSIR**	:	
Plaintiff	:	**NO. 18-5458**
	:	
v.	:	
	:	
PHILADELPHIA VASCULAR	:	
INSTITUTE LLC, *et al.*	:	
Defendants	:	

NITZA I. QUIÑONES ALEJANDRO, J. MARCH 29, 2024

MEMORANDUM OPINION

INTRODUCTION

Realtor Dr. Aaron Shiloh filed this *qui tam*[1] action against Defendants James McGuckin, M.D., ("Defendant McGuckin") and Philadelphia Vascular Institute, LLC, asserting violations of the False Claims Act (the "FCA"), 31 U.S.C. § 3729 *et seq*. On February 28, 2023, the United States of America[2] (the "Government") filed a notice of intervention, indicating its decision to intervene on behalf of the relator, (ECF 27), and on May 1, 2023, filed the complaint in intervention against Defendant McGuckin and his practices and management companies,[3]

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[1] "*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means 'who pursues this action on our Lord the King's behalf as well as his own.'" *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 768 n.1 (2000). A private person, called a relator, brings an action "'for the person and for the United States Government against' the alleged false claimant, 'in the name of the Government.'" *Id.* at 769 (quoting 31 U.S.C. § 3730(b)(1)).

[2] The Government brings this action on behalf of the United States Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program ("Medicare"), 42 U.S.C. §§ 1395 *et seq.*; and the United States Office of Personnel Management ("OPM"), which administers the Federal Employee Health Benefits Program ("FEHBP").

[3] The Government additionally brings this action against Defendants Philadelphia Vascular Institute, LLC ("Defendant PVI") and Pennsylvania Vascular Institute, PC ("Defendant PA PC") (collectively, "Management Defendants"); and Lehigh Valley Vascular Institute LLC ("Defendant LVVI"), PA Vascular

(collectively "Defendants"), asserting claims under the FCA for, *inter alia*, knowingly submitting or causing the submission of false claims for reimbursement to federal health care programs for medically unnecessary invasive vascular procedures, knowingly making false statements to the government related to those procedures, and violating the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b), (g), (ECF 32).

Before the Court is Defendants' motion to dismiss filed pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6) and Rule 9(b). (ECF 36). The Government opposes the motion. (ECF 40). The issues raised in the motion have been fully briefed and are ripe for disposition.[4] For the reasons set forth, Defendants' motion is denied.

BACKGROUND

When ruling on a motion to dismiss, this Court must accept as true the well-pleaded allegations in the Government's complaint. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). The facts relevant to the motion to dismiss are summarized as follows:[5]

Overview of Medicare Payment System[6]

> Medicare is a federal program administered by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the Department of Health and Human Services ("HHS"). The Medicare program consists of four parts: A, B, C, and D. Only Part B is relevant here. Medicare Part B covers the cost of outpatient care, including physician services and ancillary services, furnished by physicians and other providers and suppliers.

Institute LLC ("Defendant PAVI"), Peripheral Vascular Institute of Philadelphia, LLC ("Defendant PVIP"), and Main Line Vascular Institute LLC ("Defendant MLVI") (collectively, "Defendant Practices"). The Government alleges Defendant McGuckin owns 100% of Management Defendants, and that Defendant PA PC owns 100% of Defendant Practice.

4 This Court has also considered Defendants' reply. (ECF 41).

5 These facts are drawn from the Government's complaint in intervention. (ECF 32).

6 (*See* Compl., ECF 32, at § III (B)).

Medicare pays only for services that are actually rendered and which are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). To this end, Medicare providers must assure that their services are rendered "economically and only when, and to the extent, medically necessary," and that their services are "of a quality which meets professionally recognized standards of health care." 42 U.S.C. §§ 1320c-5(a)(l)-(2).

After performing a Part B service, providers are required to submit a claim form to the CMS certifying, among other things, that "the services shown on this form were medically indicated and necessary for the health of the patient[.]" *See* CMS Form 1500. Relying on the veracity of these certifications, the CMS makes Medicare payments retroactively, *i.e.*, they reimburse Part B providers. When submitting a claim form, the provider includes a five-digit code ("CPT code") that identifies, for example, the diagnosis, services rendered, and the unique billing identification number. Providing accurate CPT codes on the claim form is a condition of payment from Medicare.

As a general matter, Medicare Part B covers 80% of the reasonable cost of medical services; the remaining 20% is owed by the beneficiary as a copayment obligation. Except in rare circumstances, providers are required to make a reasonable collection effort for the full 20% copayment from Medicare beneficiaries or their secondary insurers.

Factual Allegations

Defendant McGuckin is an interventional radiologist. He owns and operates multiple vascular practices across the country, including the Defendant Practices and Management Defendants. Between 2016 and 2019, Defendant McGuckin and the Defendant Practices were providing endovascular services to Medicare and FEHBP beneficiaries. Defendant McGuckin has been registered as a Medicare provider in Pennsylvania since at least 2010. Defendant Practices and Management Defendants are also registered Medicare providers in Pennsylvania.

Defendant McGuckin instructed physicians at Defendant Practices to screen all dialysis patients for Peripheral Artery Disease ("PAD").[7] He also instructed physicians to perform intravenous ultrasounds on every Medicare patient instead of using less invasive diagnostic measures. Defendants also scheduled follow up tests of asymptomatic patients at regular intervals. Defendants performed most procedures, including angioplasties, atherectomies, and stent implantations, without any prior non-invasive imaging or assessment of relevant medical histories

[7] Peripheral Artery Disease ("PAD") is the narrowing or blockage of peripheral arteries and the consequent reduction of blood flow to the legs. The standards of care for the treatment of PAD depend almost entirely on a patient's symptoms. The Government alleges at length the typical causes, escalation, and symptoms of PAD, as well as the medical standard of care and typical treatment approaches. (*See* Compl., ECF 32, at § IV (A)).

and symptoms to justify these invasive procedures. Defendant McGuckin and his staff also did not evaluate patients preoperatively. According to the Government, Defendant McGuckin's records confirm that he often overestimated the severity of patients' artery blockage to justify interventions. Patients on whom Defendant McGuckin performed an angiogram of one leg routinely were brought back for an angiogram of both legs within a few weeks, regardless of any medical indication. To convince patients to undergo these procedures, Defendant McGuckin would tell them that the procedures were necessary to "stop the chop," *i.e.*, leg amputation. Defendant McGuckin traveled throughout the state to perform these procedures. According to the Government, a review of Defendants' records further indicates that in some cases, Defendant McGuckin billed Medicare for procedures for which there was no evidence he performed the procedures at all.[8]

The Government contends that data shows that for the years 2016-2020, despite having an average practice size and number of patients, Defendant McGuckin was: ninth out of over 6,500 practitioners in Medicare Part B reimbursements for the four PAD procedure codes examined in the Government's statistical analysis; thirteenth in the number of patients billed for the codes at issue; second for amounts paid for these codes; and fourth in the number of these procedures performed. In Pennsylvania, McGuckin was first in nearly all of these categories. Defendants PVIP and PAVI are also outliers on two of the sampled CPT codes.

The United States paid Defendants at least $6.5 million for over 500 false claims related to the four CPT codes the Government sampled, by submitting claims of reimbursement to Medicare and the FEHBP for PAD procedures that were not medically necessary and/or were not properly documented.

Defendants also inappropriately waived Medicare copayments, by failing to satisfy the conditions established by Medicare to support those copayment waivers. Defendants advised patients that they would not have to pay for Defendants' services and that the insurance payments, including Medicare payments, would be treated as payment in full. At times, however, Defendants collected copayments from secondary insurances but regularly did not collect copayments from federal beneficiary patients who lacked supplemental coverage.

Defendants utilized a "Charity Policy" to waive patients' financial responsibility, *i.e.*, copayments. Specifically, the Charity Policy provided that low-income patients must complete an application for financial assistance, including federal tax returns, and submit the application prior to the scheduled date of their procedure to allow for review by Defendants. Pursuant to the Charity Policy, Defendants were supposed to send a letter of confirmation with the results of the review and place a copy in the patient's chart. While the waiver of copayments is permitted in certain circumstances, Defendants waived copayments without

[8] The Government alleges specific facts of ten sample patients to demonstrate Defendants' treatment practices and routines. (*See* Compl., ECF 32, at pp. 42-60).

> following their own Charity Policy guidelines which required approving the application prior to a patients' procedure and/or confirming their low-income status. In doing so, Defendants waived copayments in violation of federal program guidelines.[9]

LEGAL STANDARD

When considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), the court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler*, 578 F.3d at 210. The court must determine "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The complaint must do more than merely allege the plaintiff's entitlement to relief; it must "show such an entitlement with its facts." *Id.* (citations omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)) (alteration omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Id.* To survive a motion to dismiss under Rule 12(b)(6), "a plaintiff must allege facts sufficient to 'nudge [his] claims across the line from conceivable to plausible.'" *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 570).

[9] The Government alleges specific facts related to two sample patients whose copayments were completely written off as "charity," despite not having any documentation to support the "Charity Policy" write off. (*See* Compl., ECF 32, at pp. 70-72).

Rule 9(b) requires that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) ("[Rule] 9(b) requires plaintiffs to plead the circumstances of the alleged fraud with particularity to ensure that defendants are placed on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of fraud." (internal quotation marks omitted)).

The United States Court of Appeals for the Third Circuit ("Third Circuit") has made clear that Rule 9(b)'s particularity requirement necessitates more than "[a] mere inference of illegality[.]" *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 301 n.9 (3d Cir. 2011) ("[P]laintiffs must plead FCA claims with particularity in accordance with Rule 9(b)."). That is, "a [plaintiff] must establish a strong inference that the false claims were submitted." *Bookwalter*, 946 F.3d at 176 (internal citations and quotation marks omitted). "Rule 9(b)'s particularity requirement requires a plaintiff to allege 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.'" *Id.* (quoting *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016)). "Rule 9(b) does not require [plaintiffs] to plead anything more, such as the date, time, place, or content of every single allegedly false Medicare claim." *Id.*

Considering that "the purpose of Rule 9(b) is to provide defendants with fair notice of the plaintiffs' claims," the Third Circuit has held that to survive a motion to dismiss and satisfy Rule 9(b), a plaintiff asserting claims under the FCA "must provide particular details of a scheme to

submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153, 158-59 (3d Cir. 2014) (citations omitted). "Describing a mere opportunity for fraud will not suffice," and, instead, a plaintiff must provide "sufficient facts to establish a plausible ground for relief." *Id.* at 159 (citations omitted). However, a plaintiff need not "identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief." *Id.* at 156 (quoting *Wilkins*, 659 F.3d at 308).

DISCUSSION

In its complaint, the Government alleges that Defendants: (1) submitted false claims for services that were not medically necessary, not performed, and/or were not properly documented (Count I) and made or used false statements in doing so (Count II); (2) submitted claims tainted by kickbacks in the form of copayment waivers in violation of the Anti-Kickback Statute (Count III) and made or used false statements in doing so (Count IV); (3) received reimbursements from the United States under mistake of fact (Counts V-VI); and (5) were unjustly enriched by their fraudulent conduct (Count VII).

Defendants move to dismiss the Government's complaint arguing that: (1) the complaint is an improper "shotgun" pleading; (2) the Government's claims based on Plaintiffs' alleged performance of medically unnecessary procedures (Counts I, II, IV, and VI) are insufficiently pled because, at most, the Government pleads a medical disagreement; and (3) the Government's Anti-Kickback Statute claims (Counts III, IV, and VI) were not pled with sufficient specificity. These arguments are addressed in turn.

Defendants' Shotgun Pleading Argument

Defendants argue that the Government's complaint is an improper "shotgun" pleading because it contains multiple counts that adopt the allegations of all preceding paragraphs and

asserts all claims against all Defendants, making it difficult for Defendants to discern which factual allegations support which cause of action, and which Defendants took which allegedly improper actions. Defendants are mistaken.

A shotgun pleading fails to provide a defendant notice of the claims asserted. *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 582 (E.D. Pa. 2019) (citing *Hynson v. City of Chester Legal Dep't.*, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988)). A prototypical shotgun complaint is one that "offer[s] vague and conclusory factual allegations in an effort to support a multiplicity" of claims against multiple defendants. *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 860 (E.D. Pa. 2017) (quoting *Ebrahimi v. City of Huntsville Bd. of Educ.*, 114 F.3d 162, 164 (11th Cir. 1997)).

Here, although each count of the Government's complaint incorporates by refence all previous paragraphs, the Factual Background section of the complaint is divided into sections that clearly describe the factual allegations that are relevant to each claim, which implicate all Defendants. For example, Section V provides the facts underlying the Government's False Claims Act allegations premised on the submission of claims for medically unnecessary procedures. (*See* Compl., ECF 32, at § V). Similarly, Section VI of the complaint provides the facts underlying the Government's False Claims Act allegations premised on violations of the Anti-Kickback Statute. (*Id.* at § VI). Despite the incorporation of all the previously alleged facts into each count, the facts alleged are neither vague nor conclusory and, sufficiently, put Defendants on notice of the specific allegations and claims against them. *See Weiland v. Palm Beach Cnty. Sheriff's Off.*, 792 F.3d 1313 (11th Cir. 2015) (reversing the dismissal of claims that incorporated previous paragraphs because "the task of figuring out which" paragraphs of the complaint were relevant to each claim was "hardly a task at all" when the complaint was organized into subsections).

Further, the fact that all counts in the complaint are asserted against all Defendants does not invalidate the complaint. "[W]here multiple defendants are involved, the complaint should inform each defendant of the nature of the alleged participation in the fraud." *Tredennick v. Bone*, 323 F. App'x. 103, 105 (3d Cir. 2008). Here, the complaint alleges a scheme among Defendants in which Defendant McGuckin performed unnecessary medical procedures, billed Medicare and, in some instances, failed to collect the mandatory copayments owed. Defendant McGuckin's alleged misconduct occurred during his medical practice at Defendant Practices. Defendant Practices are allegedly owned by Management Defendants, which are, in turn, solely owned by Defendant McGuckin. As such, the Defendant Practices and Management Defendants acted in concert with Defendant McGuckin, therefore, the factual allegations of the scheme charged apply to all Defendants. Under these circumstances, this Court finds that the complaint informs each Defendant of their alleged participation in the fraud scheme and is not an improper shotgun pleading.

Plaintiff's False Claims Act Claims

At Counts I, II, V, and VII of the complaint, the Government asserts claims under the False Claims Act ("FCA") premised on Defendants' submission of Medicare claims for reimbursement for services that were either not medically necessary, or not performed. The FCA imposes liability upon a person who knowingly presents or causes to be presented a false or fraudulent claim for payment or approval, or who knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)-(B); *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). To state an FCA claim, a plaintiff must allege facts sufficient to plausibly show causation, falsity, knowledge

(scienter), and materiality. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citing *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182 (2016)).

Defendants argue that the Government has not met its heightened pleading burden required by Rule 9(b) for these claims because it has not pled facts sufficient to show both falsity and scienter. Specifically, Defendants contend that the Government has not and cannot meet this heightened burden because it has pled, at most, a difference in medical opinions that cannot form the basis of a false claim and has failed to plead that Defendants' purported medical opinion was objectively false.

At the outset, Defendants' argument — that the Government has pled nothing more than medical disagreements which cannot form the basis of a false claim — has been rejected by the Third Circuit. In *United States ex rel. Druding v. Care Alternatives*, the defendant provider successfully argued at summary judgment that the plaintiff had proffered nothing more than a mere difference in medical opinion between physicians to meet the plaintiff's burden with respect to falsity. 952 F.3d 89, 94 (3d Cir. 2020). In reversing the district court's grant of summary judgment and rejecting the very argument presented by Defendants in this case, the Third Circuit held:

> In analyzing the statute's text, we find the premise of the District Court's holding — that a "mere difference of opinion" is insufficient to show FCA falsity — is at odds with the meaning of "false" under the statute. We also conclude that the District Court's "objective" falsity standard improperly conflates the elements of falsity and scienter, inconsistent with the application of the FCA.

Id. at 95. Therein, the Third Circuit also rejected the same "objectively false" argument being made by Defendants here, holding:

> According to the District Court, a medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy. In other words, opinions being subjective, a differing medical conclusion regarding a patient's prognosis alone is not

> enough to show the certifying physician's determination of terminal illness was factually incorrect.
>
> We disagree with the District Court's decision to circumscribe FCA falsity to findings of factual falsity. This runs contrary to the cases in this Court, which have recognized falsity to include legal falsity. In other words, our cases instruct that FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government.

Id. at 97 (internal citations omitted). Consistent with this decision, this Court rejects Defendants' arguments.

Defendants also argue that the Government has failed to allege facts sufficient to show falsity because it has not alleged that "Defendants falsified the patient medical records or diagnoses," and has not alleged how the particular medical procedures were "outside a particular medical standard of care. . . ." (Defs.' Mot., ECF 36-1, at pp. 16-17). Defendants, however, misconstrue the falsity pleading requirement.

"There are two categories of false claims under the FCA: a factually false claim and a legally false claim." *Wilkins*, 659 F.3d at 305. "A claim is factually false when the claimant misrepresents what goods or services it provided to the Government." *Id.* A claim is legally false when a claimant knowingly falsely certifies that it has complied with a statute or regulation, compliance with which is a condition or precondition for government payment. *Id.*; *see also Petratos*, 855 F.3d at 486. The second category, legally false claims, is subcategorized into two theories of liability: "express false certification" and "implied false certification." *United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 445 (E.D. Pa. 2020).

"Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Wilkins*, 659 F.3d at 305 (quoting

Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008)). Implied false certification liability "attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.*; *see also Universal Health Servs.*, 579 U.S. at 181. For liability to attach, the defendant's false certification "about its compliance with a legal requirement [must be] 'material to the Government's payment decision.'" *Greenfield*, 880 F.3d at 94 (quoting *Universal Health Servs.*, 579 U.S. at 181). "Materiality" is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money." 31 U.S.C. § 3729(b)(4).

Here, though the Government alleges both factual and legal falsity claims, it appears that Defendants only challenge the Government's legal falsity claims, *i.e.*, those premised on the lack of medical necessity.[10] (*See* Defs.' Mot., ECF 36-1, at p. 16). In FCA cases alleging lack of medical necessity, certification to the government[11] is "false simply 'if the procedure was not reasonable and necessary under the government's definition of the phrase.'" *Druding*, 952 F.3d at 97 (quoting *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018) (finding that plaintiff-physician's opinion that defendant-cardiologist's procedures were not "reasonable and necessary" was a cognizable allegation as to whether the cardiologist's reimbursement claims were "false")); *see also United States ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949, 963 (D. Kan. 2019) (finding that the allegation that defendants were "incorrectly diagnosing

[10] Notably, the Government pled factually false claims by expressly alleging that Defendants billed Medicare for procedures without any evidence that Defendant McGuckin performed those procedures. (*See e.g.*, Compl., ECF 32, at ¶¶ 141, 148, 168, 174, 187, 194).

[11] Section 424.24 requires that all claims for "covered medical and other health services furnished by providers" include a certification that "[t]he services were medically necessary[.]" 42 C.F.R. § 424.24(g)(1).

patients or certifying that treatments were medically necessary when they actually were not" was sufficient to allege a claim for a false statement under § 3729(a)(1)(B)).

Here, the Government cites to the purported well-established medical standards of care for the treatment of PAD, offering authoritative guidelines established by multiple professional societies. (*See* Compl., ECF 32, at ¶¶ 85-110, 115-16). Accepting these allegations as true at this stage of the litigation, as this Court must, these standards establish the proper course of medical care for the treatment of PAD, a course allegedly not followed by Defendant McGuckin. The Government alleges that Defendants regularly failed to adhere to these standards and further submitted claims that included certifications that the procedures performed were medically necessary, when, in fact, they were not. (*See id.* at ¶¶ 132-140) (alleging that Defendants failed to properly assess patients' medical history and symptoms, exhaust non-invasive PAD treatments, evaluate patients preoperatively, and provide reasonable medical notes to support a need for intervention); (*see also id.* at ¶¶ 144-213) (alleging specific facts pertaining to ten patients who received invasive PAD treatments despite having no symptoms, treatment histories, and/or pre-operative testing to support the medical necessity of the invasive PAD interventions they received).[12] The complaint further alleges that Defendants were outliers compared to medical providers nationwide, ranking amongst the top practitioners and providers with respect to the number of procedures performed, reimbursements submitted, and amounts billed for the sampled CPT codes. (*See id.* at ¶¶ 215-17). This Court finds that these allegations are sufficient to plausibly assert FCA claims premised on legal falsity. *See, e.g.*, *Polukoff*, 895 F.3d at 743-44 (finding that complaint alleging that defendant performed an unusually large number of cardiac procedures,

[12] Defendants offer factual rebuttals in an effort to demonstrate that the procedures rendered were medically necessary. At this stage of the litigation, however, the Court must accept all facts in the complaint as true, so factual disputes are premature. *See United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 163 n.21 (E.D. Pa. 2012).

violating both industry and hospital guidelines, where other doctors objected to said practice, met the pleading burden under Rules 12(b)(6) and 9(b), even where defendant asserted procedures were appropriate for other indications and to prevent stroke); *see also Tra*, 403 F. Supp. 3d at 960 (finding that the Government sufficiently pled that treatments and prescriptions were false as medically unnecessary by alleging, *inter alia*, that defendant's number of prescriptions was high, certain prescriptions did not meet medically appropriate treatment standards, and Medicare does not pay for claims unless they are medically necessary).

Defendants also argue that the Government does not plead sufficient facts to plausibly show that Defendants *knowingly* submitted false claims for reimbursement. Defendants are mistaken. The FCA defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); *see also Universal Health Servs.*, 579 U.S. at 182. Importantly, the FCA "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). Additionally, "[t]he FCA's scienter element refers to [a defendant's] knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed." *United States ex rel. Schutte v. Supervalu, Inc.*, 143 S. Ct. 1391, 1399 (2023).[13]

[13] Relying on the holding in *Ruan v. United States*, 597 U.S. 450 (2022), Defendants argue that the Government does not allege that Defendant McGuckin subjectively believed that he was violating standards of care or that he knew that the services were not medically necessary. In *Ruan*, the Supreme Court of the Unites States (the "Supreme Court") rejected an objective standard and adopted a subjective standard, holding that a physician may not be convicted of criminal controlled substances violations unless the government proves that he knew or intended that his conduct was unauthorized. 597 U.S. at 467. Defendants' reliance on *Ruan* is, however, misplaced. The Supreme Court's holding in *Ruan* applies to the *mens rea* element of the criminal provision of the Controlled Substance Act and is not applicable in the civil context, including in FCA cases. *See United States v. Spivack*, 2022 WL 4091669, at *1 n.1 (E.D. Pa. Sept. 6, 2022) ("We reject [plaintiffs'] argument [that] the *mens rea* element the Court found in *Ruan* 'should be the same' in the civil context."). Accordingly, the Government need not have alleged that Defendant McGuckin knew he was violating the standard of care and performing medically unnecessary treatments.

In the complaint, the Government expressly outlines the Medicare standards that make Medicare providers, like Defendants, responsible for knowing locally acceptable standards of practice. (Compl., ECF 32, at ¶ 34). The Government also alleges that, as a condition of becoming a Medicare provider, a Part B provider must certify that they agree to comply with the Medicare laws, understand the legal conditions of reimbursement, and that they "will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." (*Id.* at ¶ 35 (quoting CMS Form 855b and CMS Form 855i)). Against this backdrop of the applicable standards, the Government alleges that:

> [Defendant] McGuckin has admitted in writing to, and been personally sanctioned for, conducting invasive vascular procedures, including angioplasty and stenting, without first conducting the required patient assessments to ensure the procedures were medically necessary, and without proper documentation of the same. He has also confirmed in writing and under oath his personal knowledge that submitting a claim to Medicare that is not sufficiently documented as being medically necessary is a false claim subject to damages and penalties under the FCA.
>
> ***
>
> McGuckin's admissions, in writing and in testimony given under oath, coupled with his self-reporting that his PAD procedures are on patients who do not meet the criteria for such invasive procedures, demonstrate that Defendants' conduct was knowing under the FCA.

(*Id.* at ¶¶ 221, 230); (*see also id.* at ¶¶ 222-229) (providing specific examples of Defendant McGuckin's knowledge of Medicare's medical necessity and documentation requirements from previous sanctions and FCA settlements). Defendant McGuckin's knowledge is further imputed to the other Defendants, as the Government alleges that Defendant McGuckin sought the reimbursements from the United States through the Defendant Practices, with the knowledge and under the management of the Management Defendants, all of which are owned by Defendant

McGuckin. In light of these allegations, the Government has met its pleading burden with respect to the requisite knowledge/scienter.

In sum, this Court finds that the Government has satisfied its heightened Rule 9(b) pleading burden with respect to falsity and knowledge and has sufficiently pled its FCA claims based on Defendants' alleged performance of medically unnecessary procedures and Defendants' submission of claims for procedures for which there is no record of performance.

Anti-Kickback Claims

At Counts III, IV, and VI of the complaint, the Government alleges that Defendants violated the Anti-Kickback Statute by waiving the required Medicare copayment from their patients. Defendants argue that the Government has not pled facts sufficient to support the kickback claims because the allegations are primarily based upon "information and belief." A careful review of the complaint, however, belies Defendants' argument. The Government expressly alleges, without qualifying with the phrase "information and belief," that Defendants submitted claims to Medicare where patients did not pay copayments. (*See e.g.*, Compl., ECF 32, at ¶ 255) ("Patient RD paid nothing for these procedures."); (*id.* at ¶ 265) ("Patient MH paid nothing for these procedures.").

Defendants also argue that the alleged waivers were not improper because they were issued under Defendants' "Charity Policy." As alleged in the complaint, Defendants Charity Policy allows for waiver of copayments under certain circumstances for certain patients, which the Medicare law permits under limited circumstances. The Government, however, specifically alleges that patients received copayment waivers under the Charity Policy without any documentation to support said waiver, directly in violation of Defendants' own policies and

Medicare laws. (*See id.* at ¶¶ 246-47, 251).[14] As such, the Government has met its burden at the pleading stage with respect to the Anti-Kickback Statute violation claims.

CONCLUSION

For the reasons stated herein, Defendants' motion to dismiss is denied. The Government has pled sufficient facts to support its False Claims Act, Anti-Kickback Statute, and unjust enrichment claims. An Order consistent with this Memorandum Opinion follows.

NITZA I. QUIÑONES ALEJANDRO, U.S.D.C. J.

[14] Defendants offer factual rebuttals in an effort to demonstrate that the waiver of copayments was proper for the sample patients that the Government alleged. At this stage of the litigation, however, the Court must accept all factual allegations as true, so factual disputes are premature. *See Spay*, 913 F. Supp. 2d at 163 n.21.